REMARKS

I. Status of the Claims and Rejections

This is in response to the Non-Final Official Action mailed October 23, 2007. Claims 1-3, 5-36, and 46-80 are currently pending, unamended, with claims 4, 37-45, and 81-85 having been previously canceled.

The independent claims (claims 1, 13, 46, 55, 74, and 78) stand rejected under 35 U.S.C. 103(a) as being obvious in light of Jhuboo et al., U.S. Patent No. 5,501,665 (Jhuboo). The remaining claims, all dependent, are variously rejected for obviousness in light of Jhuboo alone or, in some cases, in further view of Tribe et al U.S. Patent Application No. 2003/0205587 or Moberg et al U.S. Patent No. 6,485,465. For purposes of this response, Applicants focus on the rejection of the independent claims over Jhuboo as sufficient to resolve all of the rejections. Applicants reserve the right to address the dependent claims and/or present additional arguments should that become necessary.

II. Examiner Has Failed to Address the Claims as Amended

The claimed invention relates generally to detecting occlusions in a fluid line by determining first and second instantaneous force values F1 and F2, respectively, in a fluid at first and second instantaneous times T1 and T2, respectively. A slope is calculated that corresponds to the difference between F2 and F1 divided by the difference between T1 and T2. Claims 1 and 13 are method claims that provide an indication if the calculated slope departs from an expected slope relationship. Claims 46 and 55 are claims directed towards a syringe pumping system and a pumping system, respectively, in which a processor determines if the calculated slope departs from an expected slope relationship. Claims 74 and 78 are claims directed towards a pumping system and a syringe pumping

system, respectively, in which a processor initiates altering delivery of the fluid in response to determining that the slope deviates from an expected value. Thus, the claimed invention measures two instantaneous force values to calculate the slope of the line between the force values over time then analyzes the calculated slope to determine if there is an occlusion or action required.

All independent claims were initially amended in the Response filed December 29, 2006 (the "12/06 Response") to indicate that the first and second force values were instantaneous force values. Independent claims 1, 13, 46, and 55 were further amended to indicate that the expected relationship was an expected slope relationship. These amendments were made after a telephonic interview between Examiner and one of Applicants' representatives on November 30, 2006, during which it was agreed that the amendments would overcome Examiner's objections and rejections.

All independent claims were subsequently amended in the Amendment with Request for Continued Examination filed August 8, 2007 (the "8/07 Amendment") by indicating that first and second instantaneous force values F1 and F2, respectively, were determined at first and second instantaneous times T1 and T2, respectively. The amendments also indicated that a slope was calculated by dividing a difference between F2 and F1 by a difference between T1 and T2. Again, these amendments were made after a telephonic interview between Examiner and one of Applicants' representatives on May 1, 2007, during which it was agreed that the amendments would be sufficient to overcome Examiner's objections and rejections.

In the present Non-Final Office Action, Examiner repeats her prior rejections under Jhuboo, essentially verbatim, thus failing to take into account that the claims were

amended in the 8/07 Amendment to reflect the change then-agreed upon. In that regard, the present claims have not been fairly examined. Applicants are faced with responding to Examiner's positions even though not focused on the claims. If the next action is nonetheless Final, Applicants will have been deprived of the full and fair examination to which they are entitled all the while further adding to the delay in moving this case to allowance.[1] Applicants submit that the claims should be allowed, but at a minimum, if Examiner is not prepared to allow the claims, a new non-final action should be issued which directly addresses the claims as written.

III. Operational Differences Between Jhuboo and the Claimed Invention

In any event, the present rejections based on Jhuboo are simply wrong and should be withdrawn. Jhuboo is related generally to detecting an obstruction in a perfusion line in a particular manner following a particular procedure. That is important because the purpose and operational behavior of Jhuboo cannot be divorced from its disclosure. Jhuboo begins by measuring the average pressure over three consecutive intervals: P_i, P_{i+1}, and P_{i+2} (e.g., col. 4 line 55 to col. 5 line 1). Calculated changes in average pressure over those intervals (e.g., col. 5 lines 17-19 and lines 23-25) are compared to an experimental gradient multiplied by the interval being analyzed (e.g., col. 5 lines 17-39, FIG. 8 steps 130 to 134). In sum, Jhuboo determines obstructions in a perfusion line by analyzing average pressures over consecutive time intervals and comparing them to a predetermined gradient.

The claimed invention calculates a slope by determining instantaneous force values at discrete times while Jhuboo is limited to utilizing the average of force over time

[1] Applicant cannot help but note that the claims have been amended multiple times, based on agreement with Examiner that Jhuboo would thus be overcome, only to have Examiner come back and maintain the same rejections.

to calculate a gradient. In operation, the claimed invention is particularly distinct from Jhuboo because it measures the instantaneous force values at discrete times rather than averaging force values over an interval. This has an advantage by allowing the claimed invention to operate more quickly with less intensive performance requirements (particularly in processing capability and sensing speeds), thus reducing overall component cost. However, Examiner's primary allegation can be summarized to say that although Jhuboo does not disclose using "instantaneous force values," Jhuboo can be modified to calculate force values as Δt equal zero, or as the limit of Δt approaches zero. Examiner's assertions show a misunderstanding of both the purpose of Jhuboo and the reality of mathematics. Frankly, there is a significant disconnect between the present claims, how Examiner characterizes the present claims, and the disclosure of Jhuboo. Further explanation will be made clear by way of the following illustrations.

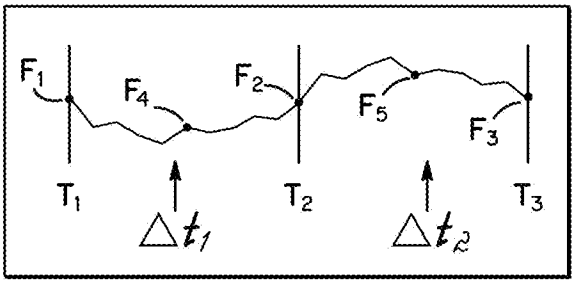

FIG. 1

FIG. 1 is an illustration of forces on a fluid over time which will be used as an possible implementation of the claimed invention in a manner corresponding to that of Jhuboo (no concession is made that the present claims are limited in this fashion, but this example is used to help explain the fallacy of Examiner's position). In this example of the claimed invention, the forces F_1, F_2, and F_3 may be measured at the three distinct times T_1, T_2, and T3, respectively, and the slopes calculated of the line from F_1 to F_2

("line F_1F_2") and the line from F_2 to F_3 ("line F_2F_3"). Significantly, the slopes of line F_1F_2 and line F_2F_3 are similar in magnitude. Thus, in this implementation, the claimed invention determines that there is no occlusion by analyzing either the slope of line F_1F_2 or line F_2F_3, avoiding useless noise that could otherwise skew results.

With respect to Jhuboo, the average forces during the intervals of $\Delta t1$ and $\Delta t2$ are measured. This requires multiple determinations of the force during each interval, then a calculation of the average force after each interval. The values for the average forces during the intervals Δt_1 and Δt_2 are shown illustratively at F_4 and F_5, respectively. To detect an obstruction, Jhuboo determines the difference between F_4 and F_5, then divides that by the difference between intervals Δt_1 and Δt_2 (mathematically, the difference between the intervals being: $(T_3-T_2)-(T_2-T_1)$). As shown in FIG. 1, Jhuboo would determine that an obstruction has occurred because of the gradient between F_4 and F_5, when in fact Jhuboo was simply averaging noise. The claimed invention would avoid this improper result by only analyzing the instantaneous values of F_1, F_2, and F_3. Additionally, the claimed invention has other methods of reducing noise or eliminating extraneous results than those disclosed in Jhuboo if measurements are taken at different times other than T_1, T_2, and T_3.

Furthermore, Jhuboo is only useful after Δt_1, Δt_2, and a third interval because it requires the calculation of at least three average force values. The claimed invention, on the other hand, is useful after T_2. Thus, Jhuboo operates in a significantly different way than the claimed invention, requiring more time, greater processing requirements, greater sensor speed, and different processes that are particular to Jhuboo to determine an obstruction. Further, the claimed invention has achieved what Jhuboo said could not be

done, as Jhuboo teaches away from the use of instantaneous force values because of the "relatively long time interval to detect an obstruction" (e.g. col. 1 lines 16-26). Examiner has failed to acknowledge that the operation of the claimed invention and Jhuboo are fundamentally different.

IV. Prior Art Rejections of the Independent Claims are Improper

Examiner sweeps these differences aside on the baseless assumption that Δt could approach zero in order to support her argument that it would have been obvious to one skilled in the art to use instantaneous force values in Jhuboo. But Examiner concedes that Jhuboo nowhere suggests using an instantaneous force value at a discrete time to determine a gradient. Indeed, Jhuboo would not work using instantaneous force values. So, Examiner engages in a bit of mathematical sophistry to reach a conclusion that is not only incorrect mathematically, but also directly at odds with the disclosure of Jhuboo. In particular, while Jhuboo always uses a time span of Δt, Examiner concludes that one with knowledge of calculus would also realize that using the limit as Δt approaches zero is also appropriate to determine instantaneous force values. While actually being at zero would give instantaneous force values, to the extent Δt is not zero, Examiner is wrong. A Δt that is greater than zero will necessarily involve taking an average, even if Δt gets so small that the force values at either end are the same. But that is not the same as taking a force measurement at a specific time and using that measurement. Instead, Examiner ultimately creates a complicated averaging system over very short intervals of time, which is not the claimed invention. Examiner has no choice but to create the fiction that Δt approaching zero is no different than Δt = zero. By way of the following illustrations this fiction will be further explained.

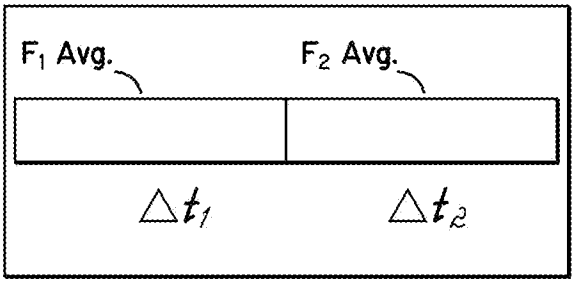

FIG. 2

FIG. 2 is a diagrammatic illustration of the consecutive measurements taken by Jhuboo with large intervals of Δt_1 and Δt_2 during which to find average force values, F_1 Avg. and F_2 Avg., respectively. As previously discussed Jhuboo determines a gradient from the difference between F_1 Avg. and F_2 Avg. divided by the difference between Δt_1 and Δt_2.

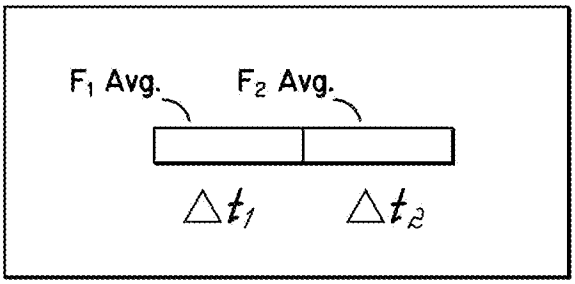

FIG. 3

FIG. 3 is a diagrammatic illustration of the consecutive measurements taken by Jhuboo with smaller intervals of Δt_1 and Δt_2 during which to find average force values, F_1 Avg. and F_2 Avg., respectively. Although Jhuboo does disclose that Δt can be small (e.g., col. 5 lines 48-50), this is only in relation to the exemplary value of one minute (e.g., col. 6 lines 7-9). Interestingly, by moving towards the direction of Δt having a value of zero (or a value approaching zero), Jhuboo fails mathematically and functionally.

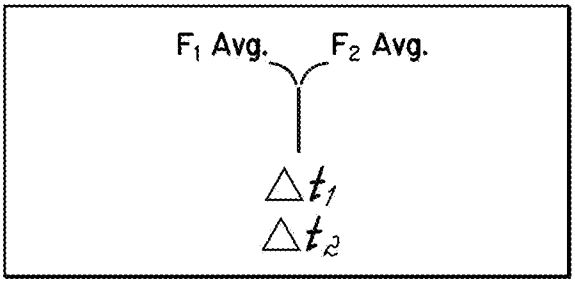

FIG. 4

FIG. 4 is an illustration of the effect that Δt having a value of zero (or a value approaching zero using Examiner's hypothesis) will have on the intervals Δt_1 and Δt_2 and average force values F_1 Avg. and F_2 Avg., respectively, in Jhuboo. To that end, the consecutive intervals use by Jhuboo, Δt_1 and Δt_2, also must collapse toward zero, such that only one value will be obtained for both intervals. Thus, By constricting Δt to zero or a value approaching zero, the value of F_1 Avg. will the same as F_2 Avg.. Any calculation of the difference between F_1 Avg. and F_2 Avg. will, in that scenario also have to approach or be zero, rendering the Jhuboo system non-functional. Furthermore, Jhuboo uses Δt as a denominator ($S=\Delta P/\Delta t$, at col. 5 line 5). Hence, were Δt_1 and Δt_2 set to zero, the result would be a gradient of infinity, again rendering Jhuboo useless. Similarly, were Δt set to a value approaching zero, Δt_1 and Δt_2 would similarly approach zero. The result would be a gradient approaching infinity, again rendering Jhuboo useless. A person skilled in the art would not have considered it obvious to make gradient comparisons with values that approach infinity as such gradient comparisons would be futile.

As illustrated by the foregoing, the claimed invention cannot be rendered obvious by Jhuboo. Despite Examiner's assertions, setting Δt to a value of zero or a value approaching zero does nothing more than render Jhuboo useless. With this in mind, it

seems painfully clear that the Examiner has simply shoehorned Applicants' invention into the disclosure of Jhuboo with the magic incantation of *KSR*. The *KSR* decision lends no support to Examiner here as *KSR* nowhere suggests that obviousness can be established by ignoring mathematical reality or extracting from a reference a concept that is at odds with the reference. Indeed, Jhuboo would not be expected to work at Δt = (or possibly even approaching) zero. As a consequence, it can only be said that the result claimed here is unexpected, which *KSR* makes clear supports patentability.

Further examples of Jhuboo failing as Δt is set to zero (or a value approaching zero), are illustrated below. In particular, as Examiner has dismissed mathematics by setting Δt to zero (or a value approaching zero), Examiner has further dismissed, without comment, the effect that this would have on Δt optimization and the relationship of Δt to noise, perfusion rate, and the gradient, as set forth in Jhuboo. However, consideration of the full disclosure of Jhuboo yields a result contrary to Examiner's position.

Jhuboo's Δt Optimization

Jhuboo discloses a process to "optimize" Δt as illustrated in FIGS. 9 and 10. In order to assert that it would have been obvious to approach or equal zero in Jhuboo's Δt, Examiner cavalierly ignores that process. That process establishes the opposite of what Examiner asserts, namely that Δt should not be set to zero or value approaching zero. FIGS. 9 and 10 of Jhuboo both show a determination of whether $|P_{i+1} - P_i| > K_1 S_0 \Delta t_i$ (e.g., see calculations in col. 6). By setting Δt to a value of zero or a value approaching zero the average pressures will always be zero or otherwise insignificantly small, destroying the illustrative process disclosed by Jhuboo. The values of Δt set to zero or a value approaching zero will prevent any optimization of Δt. Examiner has failed to provide any

motivation why a person skilled in the art would desire to set Δt to a value of zero or a value approaching zero and render future calculations of Δt meaningless. Again, when Δt is set to zero or a value approaching zero, there can be no useful average force values, destroying the purpose of Jhuboo.

Noise Effects on Δt

Setting Δt to a value of zero or a value approaching zero also ignores the real-world noise conditions that affect modern electronics. Any electronic device, system, or apparatus must take into account electrical noise that is produced by the electronics of that apparatus or its surroundings. Jhuboo discloses that if the system is experiencing noise, Δt must be large to compensate for the interference (col. 5 lines 47-48). But by asserting that Δt can be a value of zero or a value approaching zero, Examiner engages in the unrealistic fiction that all electronics operate in a perfect system. A person skilled in the art (and operating in the real world) would realize that Jhuboo requires that Δt be larger than a value of zero (or a value approaching zero) for adequate noise compensation because each component of an electronic device, system, or apparatus induces noise that must be dealt with.

Jhuboo's Relationship Between Δt and Perfusion Rates

Were Jhuboo's Δt allowed to approach or become zero, it is likely that the results would result in failure, and possibly even death to a patient. In particular, Jhuboo expresses an inverse dependency between Δt and the perfusion rate. Thus, the perfusion rate in Jhuboo is set by a user (e.g., col. 5 lines 54-55) with Δt having an inversely proportional relationship to that rate (e.g., col. 5 lines 53-54). When Δt is set to a value, such as at 1 μSec (which is certainly still well above a value approaching zero), the

perfusion rate would have to escalate to a value of 1000 L per hour (see calculations in col. 5 lines 53-55 and the exemplary value of Δt=1 minute at col. 6 lines 7-9). Correspondingly, for Δt to be set to a value of zero, the perfusion rate would seem to balloon incredibly to a value of infinity. That these perfusion rates could have devastating results on a patient is not addressed by Examiner. Examiner nonetheless blithely assumes, without any evidentiary support, that there is nothing to having Δt be a value of zero or a value approaching zero in Jhuboo. Examiner is tragically wrong.

The disclosure of Jhuboo focuses on obtaining and utilizing multiple average pressures over multiple intervals of Δt, then analyzing those average pressures and Δt ot obtain a gradient. In no place does Jhuboo suggest, or even allow for the mathematic possibility, of using a value of Δt set to zero or a value approaching zero in that context. Examiner's supposition to the contrary defies physics, mathematics, and common sense.

For the foregoing reasons, Applicants submit that independent claims 1, 13, 46, 55, 74, and 78, as well as the dependent claims, are patentable and should be allowed.[2]

CONCLUSION

In view of the foregoing, it is respectfully submitted that all the rejections are in error and should be withdrawn and the claims allowed. A formal Notice of Allowance is thus solicited.

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[2] While Applicants do not here see it necessary to address the dependent claims in any detail, one example of Examiner's treatment thereof is noted for the record. Claims 3, 14, and 57 further recite determining a steady state condition. Examiner asserts that in Jhuboo "a steady-state condition is determined (gradient constant)." Examiner does not explain what is meant by "gradient constant", but it is certainly not a "steady state condition" as claimed here. Presumably the "gradient constant" refers to the "predetermined gradient" value, "S_0,"described in Jhuboo. But S_0 cannot be considered the same as a "steady state condition" because S_0 is a numeric value "deduced experimentally by measuring the gradients of the pressure/time curve with obstructions found in the fluid line and different flow rates" (col. 5 lines 31-33). Detection of a steady state condition is described in paragraphs [0059] through [0067] of the present application, with a "steady state condition" being a time after which elevated startup slopes associated with a pre-steady state timeframe normally level off (paragraph [0065]). There is no way Jhuboo can be said to suggest, or make obvious, the determination of a steady state condition as disclosed by the present application because S_0 in Jhuboo is an experimental constant unrelated to the claimed concept of a "steady state condition."

If Examiner has any questions regarding the foregoing, or which might otherwise further this case onto allowance, Examiner is requested to contact undersigned counsel to discuss same. Moreover, if any other charges or credits are necessary to complete this communication, please apply them to Deposit Account 23-3000.

Respectfully submitted,
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